

REMARKS

In the Office Action, the Examiner rejected claims 1, 3, 5-7, 20, 21, 24, and 25 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,935,141 to Buck ("*Buck*") in view of U.S. Patent No. 6,802,971 to Gorsuch et al. ("*Gorsuch*") and U.S. Patent No. 6,045,899 to Wang et al. ("*Wang*"); and rejected claim 4 as being unpatentable over *Buck* in view of *Wang*, *Gorsuch*, and U.S. Patent No. 4,882,223 to Aptel et al. ("*Aptel*"). Applicant respectfully traverses the Section 103 rejections for the reasons provided below.

Section 103 Rejections

In the Office Action, the Examiner withdrew the previous rejection and conceded that "Kawata does not present an embodiment in the claimed range." (Office Action at 2.) However, the Examiner now takes the position that the claims are unpatentable over combinations of *Buck*, *Gorsuch*, *Wang*, and *Aptel*.

As an initial matter, Applicant submits that the Examiner has misinterpreted the disclosures of the cited references. The Examiner appears to contend that the structure of the outer surface of the membrane of the claimed invention is predominantly designed to improve filtration flow and flux of the membrane. (See, e.g., Office Action at 5-6.) Applicant respectfully disagrees.

As recited in independent claim 1, the innermost layer (not the outer surface) of the membrane is the "separation layer," which is responsible for the selectivity of the membrane (see *also* paragraphs [0026] - [0027] of Applicant's published application), and thus, relates to the flux of the membrane. To the contrary, the properties of the outer surface of the fiber membrane of the claimed invention are important for the

manufacturing, processing, and potting characteristics of the fiber rather than for the separation characteristics of an individual fiber (see, e.g., paragraphs [0021] - [0024] of Applicant's published application).

While the membrane claimed in the present application, as well as the membrane taught by *Buck*, have the selective layer on the inside of the hollow fiber (the innermost layer of the fiber of the claimed invention), *Gorsuch* teaches a membrane having the selective layer on the outside (see, e.g., col. 3, lines 9-16). *Gorsuch* specifies that "the membranes also must be designed with a morphology optimized for blood flow on the outside of the fiber and ultrafiltrate on the inner lumen of the fiber." (Col. 4, lines 52-55.) By contrast, the membrane of the claimed invention is designed for ultrafiltrate/dialysate flow on the outside (see, e.g., paragraph [0023] of Applicant's published application) and blood flow in the inner lumen of the membrane. In other words, *Buck* and *Gorsuch* deal with completely different kinds of fibers designed to function in different ways.

Further, the outer layer of the membrane of *Gorsuch* would correspond to the innermost layer of the membrane of the claimed invention, not its outer layer. Therefore, the statements related to zone 1 in *Gorsuch*, that "Gorsuch teaches that the largest leverage to obtaining optimum trans-membrane flux is the radius of the pores and the next largest lever is the porosity or number of pores/unit area (col. 4, lines 27-33)" (see Office Action at 5-6), only amount to a teaching that the selective layer of a membrane has the largest leverage on the filtration properties of a membrane. *Gorsuch* does not disclose or suggest employing a selective layer, shown as zone 1 (outer layer) in *Gorsuch*, on the innermost layer of a fiber membrane. Neither *Gorsuch* nor *Buck*

provide any motivation for modifying the fiber membranes disclosed in either reference in order to add an additional selective inner layer to control the flux of the membrane. Accordingly, one of ordinary skill in the art at the time of the invention would not have modified *Buck* based on the teachings of *Gorsuch* as proposed by the Examiner. Nor would one of skill in the art have achieved the claimed invention upon combining the teachings of *Buck* and *Gorsuch*.

Aptel also teaches a membrane having the selective layer on the outside and a structure having an increasing porosity in the direction of its inner face. (See, e.g., col. 2, lines 9-16.) The membrane of *Aptel* comprises "a macroporous layer presenting macrovoids therein substantially cylindrical radially oriented and regularly spaced with walls of homogeneous porosity in the radial direction opening on the side of the inner face of the fiber and not opening on the side of the outer face." (Col. 2, lines 22-27.)

As the sequence of layers in the membrane taught by *Aptel* is inverse to the sequence taught by *Buck*, the outer layer (selective layer) of the membrane of *Aptel* would again correspond to the inner layer of the membrane of the claimed invention, not its outer layer. Accordingly, one of skill in the art would not have been motivated to combine the teachings of *Buck* and *Aptel*. Nor would one of skill in the art have achieved the claimed invention upon combining the teachings of *Buck* and *Aptel*.

Regarding *Wang*, one of skill in the art would not look to the teachings of *Wang* at least because the reference teaches away from the claimed invention. Specifically, *Wang* is directed to flat sheet membranes rather than hollow fiber membranes. Such membranes are used to separate liquids from solids contained therein. (Abstract; col. 4, lines 10-15; and col. 7, lines 16-24.) *Wang* requires the membranes to be "substantially

free of macrovoids, which are voids that materially vary in size from the surrounding porosity." (Col. 7, lines 11-13.) This is incompatible with the finger structure present in the membranes of the claimed invention and disclosed in *Buck*, for example.

Accordingly, at least because the disclosure of *Wang* teaches away from the claimed invention, one of skill in the art at the time of the invention would not have looked to the teachings of *Wang* to modify the disclosed embodiment of *Buck*.

Applicant further notes that the values for pore diameters and pore densities found in *Wang* and recited by the Examiner refer to the skin layer, which is the selective layer of the membranes disclosed by *Wang*. These values would correspond to the innermost layer of the membrane in the claimed invention. The pores on the opposite surface of the membrane taught by *Wang* have diameters in the range of from about 5 to about 100 μm (see col. 7, lines 4-6), which are far outside the range defined by the claims of the present application.

Accordingly, *Gorsuch*, *Wang* and *Aptel* do not address the problems associated with the preparation of filter modules from hollow fiber membranes, *i.e.*, challenges of handling the fibers, preventing fibers in a bundle from adhering to each other, or potting the membrane bundle. Therefore, the one of ordinary skill in the art would not look to these references for teachings to modify the disclosed embodiment of *Buck*. Moreover, the combination of the cited references would not lead one of skill in the art to the invention recited in any of the pending claims.

For at least the aforementioned reasons, independent claim 1 is inventive over the prior art, and the Examiner should withdraw the Section 103 rejection of claim 1.

Claims 3-7, 20, 21, 24, and 25 are allowable at least due to their dependence from allowable independent claim 1.

Conclusion

In view of the foregoing remarks, Applicant respectfully requests reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account 06-0916.

Respectfully submitted,

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Dated: November 16, 2010

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